

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Li et al. Art Unit : 1647  
Patent No. : 7,579,439 Examiner : Fozia M. Hamud  
Issue Date : August 25, 2009 Conf. No. : 9466  
Serial No. : 10/749,699  
Filed : December 30, 2003  
Title : MODULATION OF IL-2 AND IL-15 MEDIATED T CELL RESPONSES

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**APPLICATION FOR PATENT TERM ADJUSTMENT UNDER 37 C.F.R. § 1.705(d)**

Patentees hereby request reconsideration of the Patent Term Adjustment (PTA) accorded the above-referenced patent. Reconsideration of the final PTA calculation to increase total PTA from 120 days to 320 days, is respectfully requested.

**REMARKS**

"A Delays" are defined as delays by the U.S. Patent and Trademark Office (PTO) under 35 U.S.C. § 154(b)(1)(A), which guarantees prompt PTO response. "B Delays" are defined as delays by the PTO under 35 U.S.C. § 154(b)(1)(B), which guarantees no more than three year application pendency. To the extent that the periods of delay overlap, the period of any term adjustment shall not exceed the actual number of days the issuance of the patent was delayed. 35 U.S.C. § 154(b)(2)(A). As outlined in Wyeth et al. v. Jon W. Dudas (580 F. Supp. 2d 138; 88 USPQ 2d 1538), the only way that these periods of time can "overlap" is if they occur on the same day. If an "A delay" occurs on one calendar day and a "B delay" occurs on another calendar day, they do not overlap and 35 U.S.C. § 154(b)(2)(A) does not limit the extension to one day. Id.

The PTA for the instant patent, as currently calculated and shown on the face of the patent, apparently relies on the premise that the application was delayed under 35 U.S.C. § 154(b)(1)(B) *before* the initial three-year period expired. The Wyeth v. Dudas court determined that this construction cannot be squared with the language of 35 U.S.C. § 154(b)(1)(B), which applies "if the issue of an original patent is delayed due to the

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I hereby certify that this paper was filed with the Patent and Trademark Office using the EFS-WEB system on this date: October 26, 2009.

failure of the United States Patent and Trademark Office to issue a patent within 3 years.” “B delay” begins only after the PTO has failed to issue a patent within three years, not before. Id.

#### REVIEW OF PATENT TERM ADJUSTMENT CALCULATION

##### “A Delay”

A first PTO action was due on or before February 28, 2005 (the date that is fourteen months after December 30, 2003, the date on which the application was filed). The PTO mailed the first non-final Office Action on April 19, 2006, thereby according a PTO Delay of 415 days. Patentees do not dispute the PTO’s calculation for this “A Delay” from March 1, 2005 (the day after the date that is fourteen months after the date on which the application was filed), to April 19, 2006. See 37 C.F.R. §§ 1.702(a)(1) and 1.703(a)(1).

In view of the period of “A Delay” detailed above, the total “A Delay” for this patent should be calculated as 415 days.

##### “B Delay”

The period beginning on December 31, 2006 (the day after the date that is three years after December 30, 2003, the date on which the application was filed), and ending August 25, 2009 (the date the patent was issued), is 969 days in length.

“B Delay” may not include the number of days in the period beginning on the date on which a Request for Continued Examination was filed and ending on the date the patent was issued. In the present application, a Request for Continued Examination was filed on March 3, 2008, and the patent issued on August 25, 2009, resulting in a period of 540 days that must be excluded from the three year delay calculation. See 37 C.F.R. §§ 1.702(b)(1) and 1.703(b)(1).

In addition, “B Delay” may not include the number of days in the period beginning on the date on which a Notice of Appeal was filed and ending on the date of filing of a Request for Continued Examination. In the present application, a Notice of Appeal was filed on August 1, 2007, and a Request for Continued Examination was filed by Patentees on

March 3, 2008, resulting in a period of 215 days that must be excluded from the three year delay calculation. See 37 C.F.R. §§ 1.702(b)(4) and 1.703(b)(4).

In view of the periods of "B Delay" detailed above, the total "B Delay" for this patent should be calculated as 214 days (i.e., 969 days minus 540 days minus 215 days). The PTO calculated 14 days of delay for issuance of a patent more than three years after filing. Patentees respectfully submit that the PTO's calculation of this "B Delay" is incorrect and that the correct PTO Delay for issuance beyond three years from filing is 214 days. See 37 C.F.R. §§ 1.702(b) and 1.703(b).

**Overlap of "A Delay" and "B Delay"**

As detailed above, "A Delay" accumulated during the following period:

March 1, 2005, to April 19, 2006.

As detailed above, "B Delay" accumulated during the following period:

December 31, 2006, to August 1, 2007.

As such, the periods of "A Delay" and "B Delay" do not overlap (i.e., occur on the same calendar day).

**Applicant Delay**

A reply to an Office Action was due on or before July 19, 2006 (the date that is three months after April 19, 2006, the date on which the Office Action was mailed). Patentees filed a response to the Office Action on October 23, 2006, thereby according an Applicant Delay of 96 days. Patentees do not dispute the PTO's calculation for this Applicant Delay from July 20, 2006 (the day after the date that is three months after the date on which the Office Action was mailed), to October 23, 2006. See 37 C.F.R. § 1.704(b).

A reply to an Office Action was due on or before May 2, 2007 (the date that is three months after February 2, 2007, the date on which the Office Action was mailed). Patentees filed a response to the Office Action on August 1, 2007, thereby according an Applicant Delay of 91 days. Patentees do not dispute the PTO's calculation for this Applicant Delay from

May 3, 2007 (the day after the date that is three months after the date on which the Office Action was mailed), to August 1, 2007. See 37 C.F.R. § 1.704(b).

A reply to an Office Action was due on or before September 20, 2008 (the date that is three months after June 20, 2008, the date on which the Office Action was mailed). Patentees filed a response to the Office Action on December 22, 2008, thereby according an Applicant Delay of 93 days. Patentees do not dispute the PTO's calculation for this Applicant Delay from September 21, 2008 (the day after the date that is three months after the date on which the Office Action was mailed), to December 22, 2008. See 37 C.F.R. § 1.704(b).

Patentees filed an Amendment Pursuant to 37 C.F.R. § 1.312 on July 1, 2009, subsequent to the mailing of the Notice of Allowance. The PTO mailed a response to the Amendment Pursuant to 37 C.F.R. § 1.312 on July 29, 2009. Patentees were accorded a delay of 29 days for this post-allowance filing. Patentees do not dispute the PTO's calculation for this Applicant Delay from July 1, 2009 to July 29, 2009. See 37 C.F.R. § 1.704(c)(10).

In view of the periods of Applicant Delay detailed above, the total Applicant Delay for this patent should be calculated as 309 days (i.e., the sum of 96 days, 91 days, 93 days and 29 days).

#### Terminal Disclaimer

This patent is not subject to a terminal disclaimer.

#### Conclusion

In consideration of the events described above, Patentees believe the PTA calculation of 120 days is incorrect. As such, Patentees respectfully request reconsideration of the PTA in the following manner:

- 1) Total PTO Delay should be calculated as 629 days (i.e., the sum of 415 days of "A Delay" and 214 days of "B Delay");
- 2) Total Applicant Delay should be calculated as 309 days (i.e., the sum of 96 days, 91 days, 93 days and 29 days); and
- 3) Total PTA should be calculated as 320 days.

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Attorney's Docket No.: 13985-0057002 / BIDMC #404

The fee of \$200 required under 37 C.F.R. § 1.18(e) is being submitted herewith. Please apply any other required charges or credits to Deposit Account No. 06-1050, referencing attorney docket number 13985-0057002.

Respectfully submitted,

/Gretchen L. Temeles/

Date: October 26, 2009

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